



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#12

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Food and Drug Administration

Re: SUPPRELIN

Docket #92E-0133

DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

Charles E. Van Horn
Patent Policy and Projects Administrator
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, D.C. 20231

Dear Mr. Van Horn:

This is in regard to the application for patent term extension for U.S. Patent No. 4,244,946 filed by The Salk Institute for Biological Studies under 35 U.S.C. 156. The human drug product claimed by the patent is SUPPRELIN (histrelin acetate), which was assigned New Drug Application (NDA) No. 19-836.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the active ingredient, histrelin acetate.

The NDA was approved on December 24, 1991, which makes the submission of the patent term extension application on February 21, 1992, timely within the meaning of 35 U.S.C. 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. 156(d)(2)(A), we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Douglas D. Busch, Esq.
Fitch, Evan, Tabin & Flannery
135 S. LaSalle Street, Suite 900
Chicago, IL 60603